

Appl. No. 10/802,166
Atty. Docket No. 9184M&
Amdt. dated June 7, 2012
Reply to Office Action of December 7, 2011
Customer No. 27752

REMARKS

Claim Status

Claims 1, 3, 7-13, 18-25 and 27 are pending in the present application.

Claims 1, 12, 13 and 27 have been amended to comprise a basic zinc carbonate containing an impurity. Support for this amendment is found in the specification at page 6, lines 5-7. No additional claims fee is believed to be due.

It is believed these changes do not involve any introduction of new matter. Consequently, entry of these changes is believed to be in order and is respectfully requested.

Claim Rejections – 35 USC 112

Claims 1, 3, 7-13, 18-25 and 27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter which is not described in the specification in such a way as to reasonably convey to one of skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants respectfully traverse this assertion.

The present invention's claims recite subject matter included in the originally filed specification; therefore it was clearly in possession of the inventor at the time the application was filed.

A. “Although [the applicant] does not have to describe exactly the subject matter claimed,...the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” *In re Gosteli*, 872 F. 2d 1008, 1012, 10 U.S.P.Q. 2d (BNA) 1614, 1618 (Fed. Cir. 1989) (citations omitted). “The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon ‘*reasonably conveys* (emphasis added) to the artisan that the inventor has *possession* (emphasis added) at that time of the later claimed subject matter.” *VAS-CATH INCORPORATED AND GAMBRO, INC., v. SAKHARAM D. MAHURKAR, and QUINTON INSTRUMENTS COMPANY*, 935

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F.2d 1555, 1991 U.S. App. Lexis 11500, 19 U.S.P.Q. 2D (BNA) 1111 ((Fed. Cir., June 7, 1991).

The standard for the written description requirement, as stated above is that the inventor has possession at the time of the filing of the patent application. Applicants state that they were clearly in possession of the claimed invention at the time of filing, in view of Claims 1, 3, 7-13, 18-25 and 27, as currently amended, which were clearly in the inventors *possession* (emphasis added) at the time the present application was filed, as demonstrated in the following:

The specification, as originally filed, states on page 6, first full paragraph:

--Basic zinc carbonate, which also may be referred to commercially as "Zinc Carbonate" or "Zinc Carbonate Basic" or "Zinc Hydroxy Carbonate", is a synthetic version consisting of materials similar to naturally occurring hydrozincite. The idealized stoichiometry is represented by $Zn_5(OH)_6(CO_3)_2$ but the actual stoichiometric ratios can vary slightly and other impurities may be incorporated in the crystal lattice.--

Applicants clearly have demonstrated and met the standard and pass the test for sufficiency of support in a patent application as the disclosure of the application as relied upon '*reasonably conveys* (emphasis added) to the artisan that the inventor has *possession* (emphasis added) at that time of the later claimed subject matter.

Claims 1, 3, 7-13, 18-25 and 27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for basic zinc carbonate, does not reasonably enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims without an undue amount of experimentation. Applicants respectfully traverse this assertion.

The present invention's claims and specification satisfy the enablement requirement as one of skill in the art, after reading the specification, could practice the claimed invention without undue experimentation.

- A. The enablement requirement is set forth in the first paragraph of section 112 of title 35, which provides in pertinent part that the specification shall describe “the manner and process of making and using [the invention], in such clear and concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use [the invention]. The enablement requirement is satisfied when one skilled in the art, after reading the specification, could practice the claimed invention without undue experimentation. *Wands*, 858 F.2d at 736-37. *AK STEEL CORPORATION v. SOLLAC AND UGINE*, 344 F.3d 1234; 2003 U.S. App. Lexis 19640; 68 U.S.P.Q.2D (BNA) 1280.
- B. Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The determination of what constitutes undue experimentation in a given case requires the application of a standard of reasonableness, having due regard. The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is *merely routine* (emphasis added), *or* if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. In re *JACK R. WANDS, VINCENT R. ZURAWSKI, JR., and HUBERT J. P. SHOEMAKER* No. 87-1454 858 F.2d 731; 1988 U.S. App. LEXIS 13208; 8 U.S.P.Q.2D (BNA) 1400.

The specification, as originally filed, states on page 6, first full paragraph:

--Basic zinc carbonate, which also may be referred to commercially as "Zinc Carbonate" or "Zinc Carbonate Basic" or "Zinc Hydroxy Carbonate", is a synthetic version consisting of materials similar to naturally occurring hydrozincite. The idealized stoichiometry is represented by $Zn_5(OH)_6(CO_3)_2$ but the actual stoichiometric ratios can vary slightly and other impurities may be incorporated in the crystal lattice.--

One of skill in the art readily recognizes and understands the term “impurities”. Any general analysis or test to confirm whether a basic zinc carbonate is “a basic zinc carbonate

containing an impurity”, as currently amended, is well within routine experimentation conducted by one of skill of the art. The analysis is simply a yes or no analysis – as the present invention requires a basic zinc carbonate containing an impurity, in direct contrast to the Bhat et al. reference which teaches and requires the *monophasic* zinc hydroxycarbonate prepared by the process of Bhat’s invention has a structure that is similar to that of hydrozincite *without any impurity phases*. There is no requirement to further define or exemplify any or all possible impurities. Further there is no requirement that the specification provide scientific data or working examples or embodiments with respect to the analysis or characterization of an impurity. There is no requirement to exemplify each and every claim element.

As stated above, --the determination of what constitutes undue experimentation in a given case requires the application of a standard of reasonableness, having due regard. The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is *merely routine* (emphasis added) --. In the present invention, it is merely routine experimentation for one of skill in the art to determine if a basic zinc carbonate material contains an impurity or does not contain an impurity.

Rejection Under 35 U.S.C. §103(a) Over WO 01/00151 (hereinafter “Gavin et al.”) and WO 96/25913 (hereinafter “Bhat et al.”)

Claims 1, 3, 7-13, 18-25 and 27 have been rejected under 35 U.S.C. §103(a) as being unpatentable over WO 01/00151 (hereinafter “Gavin et al.”) and WO 96/25913 (hereinafter “Bhat et al.”).

The Office Action concedes that Gavin et al. do not expressly teach a composition comprising the zinc-containing layered material basic zinc carbonate as instantly claimed, nor zinc carbonate hydroxide, hydrozincite, zinc copper carbonate hydroxide, aurichalcite, copper zinc carbonate hydroxide, rosasite, phyllosilicate containing zinc ions, layered double hydroxide, hydroxy double salts and mixtures thereof. The Office Action however asserts that the deficiency in Gavin et al. is cured by the teachings of Bhat et al. It is further asserted that one of ordinary skill in the art would have been motivated to do this because Gavin et al.

suggest adding zinc salts to the composition, but not specifically basic zinc carbonate and alleges that Bhat et al. cures this deficiency by teaching the synergistic action of zinc hydroxycarbonate with antidandruff actives like zinc pyrithione in shampoos. The Office action further asserts that the ‘zinc lability’ is an intrinsic property of the zinc salts of Gavin et al. since they are the same as instantly claimed. Applicants respectfully traverse this rejection.

Gavin et al. discloses a topical composition for the treatment of antimicrobial infections on the skin or scalp which includes a polyvalent metal salt of pyrithione, such as zinc pyrithione and a metal ion source. According to Gavin et al. the metal ion source can be a zinc salt. Suitable zinc salts are listed at page 7, first paragraph of Gavin et al. However, none of the zinc salts disclosed in Gavin et al. are zinc-containing layered materials as required by the instant claims. In fact, Gavin et al. is completely silent as to the use of any zinc-containing layered materials for any purposes. In this regard, the Office Action cites Bhat et al. and asserts that one skilled in the art would add the zinc hydroxycarbonate disclosed in Bhat et al. to the composition disclosed in Gavin et al. to allegedly arrive at the claimed invention. Applicants respectfully traverse the rejections.

Bhat et al. in WO 96/25913 describes the preparation and use of a material termed “monophonic zinc hydroxycarbonate.” As described by Bhat et al., hydrozincite (naturally occurring) and basic zinc carbonate are equivalent names for zinc hydroxycarbonate (Page 1, lines 23-24 and line 35). The term “monophasic” is defined (Page 1, lines 29-33) as “without any other impurity phases ... present ...”.

Applicants submitted a Declaration on June 22, 2011 under 37 C.F.R. 1.132 from James R. Schwartz in support against the previous and present Office Action assertions.

In the 1.132 Declaration submitted, to establish the impact that changes in zinc lability of basic zinc carbonate materials has on efficacy, an *In Vivo* Malassezia Automated Counting (IMAC) data from a study was correlated to the measured zinc lability values of various basic zinc carbonate materials found in the present invention and further discussed in the previous filed 1.132 Declaration of September 30, 2010.

Data from the *In Vivo* Malassezia Automated Counting (IMAC) method measures the ability of an anti-dandruff product to reduce the population of Malassezia yeast on the scalp. There is a very strong relationship between reduction in Malassezia levels and resultant clinical efficacy (reduction in flake symptoms). Thus IMAC Malassezia reduction is a proxy measurement for anti-dandruff efficacy.

In this IMAC Study, shampoo prototypes that differed only in the source of the basic zinc carbonate were evaluated for *in vivo* Malassezia reduction capability. This data is tabulated in the 1.132 Declaration in comparison to the zinc lability data for basic zinc carbonate materials of different origin and disclosed in the present invention, namely Bruggemann, Elementis, and Cater. Bruggemann is a basic zinc carbonate containing an impurity, wherein Elementis and Cater are more *without any other impurity* phases or monophasic.

As demonstrated in the Table 1 and Graph 1 of the 1.132 Declaration, there is a significant reduction in Malassezia count for Bruggemann at 251.2 when compared to Cater at 155.7 and Elementis at 214.1. The data indicates a strong correlation between *zinc lability* and product efficacy, as expected from the mechanistic understanding: zinc lability is a measure of the ability of a material to release zinc ions.

Applicants re-assert that a basic zinc carbonate *without any other impurity* phases or monophasic, for example wherein Elementis and Cater are more *without any other impurity* phases or monophasic when compared to Bruggemann, do not possess the same efficacy as a basic zinc carbonate containing an impurity, such as Bruggemann as evidenced by the supporting data in the 1.132 Declaration. Such differences of basic zinc carbonate without impurities (monophasic such as Cater and Elementis) vs. basic zinc carbonate containing an impurity (e.g. Bruggemann) are important to the behavior of basic zinc carbonate, as the higher purity materials (closer to monophasic) have lower IMAC Efficacy (Reduction in Malassezia Count), as demonstrated in Table 1 and Graph 1.

As the 1.132 Declaration previously states, this data demonstrates that Bruggemann-type basic zinc carbonate materials which contain an impurity, are an important attribute of the claimed invention to achieve high performance.

Further, there is no motivation to combine the teaching of Gavin et al. and Bhat et al. and arrive at the claimed invention, as neither Gavin et al. nor Bhat et al. disclose a basic zinc carbonate containing an impurity. Accordingly, the rejection is untenable and should be withdrawn.

Bhat et al. *clearly states* that the monophasic zinc hydroxycarbonate prepared by the process of Bhat's invention has a structure that is similar to that of hydrozincite *without any impurity phases* as may be present in the mineral. Based on this disclosure, there is no basis for suggesting that an impurity of any kind can be included in the zinc hydroxycarbonate disclosed in Bhat et al. In clear terms, Bhat et al. states that the monophasic zinc hydroxycarbonate prepared by the process of Bhat's invention is *without any impurity phases*. Therefore, Applicant is perplexed that the Office Action asserts that it cannot agree with Bhat et al. *very clear definition* that the monophasic zinc hydroxycarbonate is without any impurity phases. In direct contrast, the Office Action asserts that this argument is not persuasive because the absence of an impurity phase does not necessarily mean that an impurity itself is not present. The Office Action further asserts that if the impurity phase can be measured then it is logical to reason that enough impurity is present to be detected by that method. The Office Action further asserts that, however, if an impurity phase is not present that does not unequivocally mean that an impurity itself is not present because the impurity can be present in an amount below the method detection limits and another method, such as elemental analysis which is routinely performed by analytical chemist, is required to ascertain if the sample is indeed pure or not. Applicants re-assert that Bhat et al. has clearly defined this material as "monophasic" defined (Page 1, lines 29-33) as **"without any other impurity phases..."**. Based on this disclosure, there is no basis for suggesting that an impurity *of any kind*, can be included in the zinc hydroxycarbonate disclosed in Bhat et al. Therefore, the burden resides with the patent office to demonstrate that the Baht et al. disclosure, definition and requirement is not correct.

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Gavin et al. and Bhat et al. do not disclose all of the claim limitations of the present invention, and has not established a prima facie case of obviousness. Accordingly, the rejection is untenable and should be withdrawn.

Double Patenting

1) Claims 1, 3, 7-13, 18-22 and 25 have been provisionally rejected on the ground of nonstatutory obvious-type double patenting over claims 1, 2, 8-12, 16-32 and 34-39 of copending Application No. 11/602,770. This co-pending application is jointly owned by The Procter & Gamble Company and Arch Chemicals, Inc. As all of the rejections are provisional, Applicants will respond if and when any allowable subject matter is identified. Therefore, Applicants requests that the provisional, obvious-type double patenting rejection be held in abeyance, until indication of allowable subject matter.

2) Claims 1, 3, 7-13, 18-22 and 25 have been provisionally rejected on the ground of nonstatutory obvious-type double patenting over claims 1, 2, 9, 13-30, 35 and 37-40 of copending Application No. 11/890,684.

Claim 1 of the Application 11/890,684 is directed to a composition comprising an effective amount of a particulate zinc material; an effective amount of a surfactant including a surfactant with an anionic functional group; an effective amount of a pyrithione or a polyvalent metal salt of a pyrithione; from about 0.025% to about 5% by weight of a water soluble or dispersible, cationic, non-crosslinked, conditioning homopolymer having a cationic charge density of from about 2 meq/gm to about 10 meq/gm; and from about 20% to about 95% of an aqueous carrier, by weight of said composition.

In contrast, the instant invention is directed to a composition comprising from about 0.001% to about 5 % of a zinc-containing layered material wherein the zinc-containing layered material is a basic zinc carbonate containing an impurity; from about 10 % to about 50% of a

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surfactant including a surfactant with an anionic functional group; from about 0.01% to about 5% of a pyrithione or a polyvalent metal salt of a pyrithione; wherein the basic zinc carbonate containing an impurity has a relative zinc lability of greater than about 15% and further wherein the ratio of surfactant to basic zinc carbonate containing an impurity is greater than or equal to 2 to 1. Applicants point out that Claim 1 above, as now amended, is the same as Claim 26, now canceled. Claim 26 has not been included in this obvious type double patenting rejection.

The currently claimed invention does not require from about 0.025% to about 5% by weight of a water soluble or dispersible, cationic, non-crosslinked, conditioning homopolymer having a cationic charge density of from about 2 meq/gm to about 10 meq/gm, as required in the '684 application.

It remains well-settled law that an obviousness rejection requires at least a suggestion of *all* of the claim elements. See MPEP §2143.03. Where general conditions of a claim are disclosed in the prior art, optimum or workable ranges may be determined by routine experimentation. M.P.E.P. §2144.05 II A (citing *In re Aller*, 220 F.2d 454, 456; 105 U.S.P.Q. 233, 235 (CCPA 1955).) However, the parameter being optimized must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. M.P.E.P. §2144.05 II.B (citing *In re Antonie*, 559 F.2d 618, 195 U.S.P.Q. 6 (C.C.P.A. 1977).) Thus, the M.P.E.P. requires that only result-effective variables can be optimized. Applicants respectfully submit that nonstatutory obvious-type double patenting rejection is insufficient to establish a *prima facie* case of obviousness under the result-effective variable analysis.

First, the present invention does not establish a *prima facie* case of obviousness because it does not teach or suggest all of the claim limitations of copending Application 11/890684, each of which requires a from about 0.025% to about 5% by weight of a water soluble or dispersible, cationic, non-crosslinked, conditioning homopolymer having a cationic charge density of from about 2 meq/gm to about 10 meq/gm.

In the '684 application, the surprising discovery that compositions combining certain water soluble or dispersible, cationic, non crosslinked, deposition polymers in combination with surfactants form microscopically-phase separate lyotropic liquid crystals suspended in an aqueous surfactant phase is **a result-effective variable**. In use, the dispersed, concentrated polymer lyotropic liquid crystal phase provides improved hair and skin conditioning. Therefore, there is no disclosure in the present invention that establishes that certain water soluble or dispersible, cationic, non crosslinked, deposition polymers in combination with surfactants form microscopically-phase separate lyotropic liquid crystals suspended in an aqueous surfactant phase **is a result-effective variable, i.e., a variable which achieves a recognized result**.

Further, the '684 application is not directed to or requires a relative zinc lability of greater than about 15% for a basic zinc carbonate containing an impurity. Yet further, the '684 application does not require a zinc-containing layered material *wherein the zinc-containing layered material is a basic zinc carbonate containing an impurity* or a ratio of surfactant to basic zinc carbonate containing an impurity of greater than or equal to 2:1. In contrast, the currently claimed invention requires the limitation of *a zinc-containing layered material wherein the zinc-containing layered material is a basic zinc carbonate containing an impurity*. Therefore, according to the analysis provided above, these parameters being optimized must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. The '684 application does not recognize either of these parameters as a result-effective variable, i.e., a variable which achieves a recognized result, which must be achieved before the determination of the optimum or workable ranges of said variable characterized as routine experimentation.

A basic zinc carbonate without any other impurity phases or monophasic, such as those from Elementis and Cater, do not possess the same efficacy as a basic zinc carbonate containing an impurity, such as Bruggemann as evidenced by the supporting data in the 1.132 Declaration.

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These 2 claim sets are patentably distinct and each of the specification and *data* demonstrate that the determination of liquid crystal phase in the '684 application or the ratio of surfactant to basic zinc carbonate containing an impurity and relative zinc lability as required in the currently claimed invention are *not a matter of routine optimization based on the result-effective variable analysis above*.

Therefore, Applicants respectfully request reconsideration and removal of this double patenting rejection.

3) Claims 1, 3, 7-13 and 18-25 have been provisionally rejected on the ground of nonstatutory obvious-type double patenting over claims 1-5, 11-27 and 33-46 of copending Application No. 11/899,106.

Applicants respectfully submit that Application No. 11/899,106 is no longer pending and was abandoned as of 3/26/2012. Therefore, the nonstatutory obvious-type double patenting is now moot. Applicants respectfully request reconsideration and removal of this double patenting rejection.

Conclusion

In light of the above remarks, it is requested that the Examiner reconsider and withdraw the rejections based on 35 U.S.C. 112 and 103(a). Early and favorable action in the case is respectfully requested.

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This response represents an earnest effort to place the application in proper form and to distinguish the invention as now claimed from the applied references. In view of the foregoing, reconsideration of this application, entry of the amendments presented herein, and allowance of Claims 1, 3, 7-13, 18-25 and 27 is respectfully requested.

Respectfully submitted,

THE PROCTER & GAMBLE COMPANY

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